

APR - 8 2004

**510(k) Summary**

K040644  
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**NAME OF FIRM:** DePuy Orthopaedics, Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, IN 46581-0988

**510(k) CONTACT:** Rebecca L. Lennard  
Project Engineer

**TRADE NAME:** DePuy Ceramic Femoral Head

**COMMON NAME:** Ceramic Femoral Ball Prosthesis

**CLASSIFICATION:** 888.3353: Hip joint femoral metal/ceramic/polymer,  
semi-constrained cemented or nonporous,  
uncemented prosthesis;  
**Class II**

**DEVICE PRODUCT CODE:** 87 LZO

**SUBSTANTIALLY EQUIVALENT  
DEVICE:** DePuy Ceramic Femoral Heads, K031803

**DEVICE DESCRIPTION AND INTENDED USE:**

The DePuy Ceramic Femoral Head is composed of an alumina composite material and is available in a 36mm head diameter with a +12-offset option. The internal bore of the ceramic femoral head, which is designed to interlock with the external taper on the femoral hip stem, is available in a 12/14 Articul/eze taper option.

The ceramic head is designed to mate with a corresponding DePuy femoral hip stem and provide the femoral articular surface of a total hip replacement.

**INDICATIONS FOR USE:**

The DePuy Ceramic Femoral Head is indicated for use as the femoral head component in total hip arthroplasty procedures. Total hip arthroplasty is intended to provide increased patient mobility and to reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

DePuy considers the Ceramic Femoral Head to be substantially equivalent to the DePuy Ceramic Femoral Heads submitted in K031803 based on similarities in design, same material composition, same sterilization and packaging methods, same intended use/indications for use, and similar labels.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Rebecca L. Lennard  
Project Engineer  
DePuy Orthopaedics, Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

Re: K040644  
Trade/Device Name: DePuy Ceramic Femoral Head  
Regulation Number: 21 CFR 888.3353  
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or  
nonporous uncemented prosthesis  
Regulatory Class: II  
Product Code: LZO  
Dated: March 10, 2004  
Received: March 11, 2004

Dear Ms. Lennard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

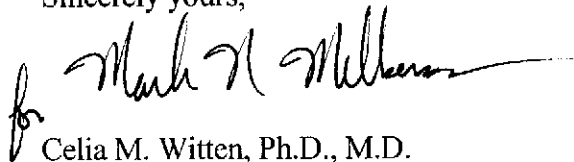
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Rebecca L. Lennard

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K040644  
Device Name: DePuy Ceramic Femoral Head

### Indications for Use:

The DePuy Ceramic Femoral Head is indicated for use as the femoral head component in total hip arthroplasty procedures.

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
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4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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(Posted November 13, 2003)

510(k) Number K040644